PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY

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To:

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J. A. KEMP & Co
REC'D 15 OCT 2001
Action to be taken SA

CONFIRMATION

date already advised

INVITATION TO RESTRICT OR TO PAY ADDITIONAL FEES

(PCT Article 34(3) (a) and Rule 68.2)

	Date of mailing *(Day/month/year)* 09.10.2001
Applicant's or agent's file reference N.77933A JCI	**REPLY OR PAYMENT DUE** within 1 month(s) from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/03760	02/10/2000	01/10/1999

International Patent classification (IPC) or national Patent classification:
G01N33/68

Applicant
ISIS INNOVATION LIMITED et al.

1. This International Examining Authority

   (i) considers that **the international application does not comply with the requirements of unity of invention** (Rule 13.1, 13.2 and 13.3) for the reasons indicated in the Annex.

   (ii) therefore considers that there are **3 inventions** claimed in the international application as indicated in the Annex.

   (iii) recalls that claims relating to inventions in respect of which no international search report has been established need not be the subject of international preliminary examination (Rule 66.1 (e)).

2. Consequently the applicant is hereby **invited**, within the time limit indicated above, **to restrict the claims** as suggested under item 3, below, **or to pay** the amount indicated below:

EUR 1533.00	x	002	=	EUR 3066.00
Fee per additional invention		number of additional inventions		total amount of additional fees

   The applicant is informed that, according to Rule 68.3 (c), **the payment of any additional fee may be made under protest**, i.e. a reasonned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. **If the applicant opts to restrict the claims**, this Authority suggests the restriction possibilities indicated in the Annex, which in its opinion would be in compliance with the requirement of unity of invention.

4. **In the absence of any response** from the applicant, this Authority will establish the international preliminary examination report on those parts of the international application indicated in the Annex which, in the opinion of this Authority appear to relate to the main invention.

Name and mailing adress of the international preliminary examination authority:	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	GONCALVES M L F C Telephone No. +49 89 2399-8127

Form PCT/IPEA/405 (July 1992)

INVITATION TO RESTRICT OR TO PAY ADDITIONAL FEES

International application No. PCT/GB00/03760

1. The wording of claim 1 is such that the subject-matter the claim is very broad, and consequently lacks novelty regarding the disclosures in the following documents cited in the search report.

D1: O'KEEFFE J ET AL: "T cell proliferation, MHC class II restriction and cytokine products of gliadin-stimulated peripheral blood mononuclear cells (PBMC)." CLINICAL AND EXPERIMENTAL IMMUNOLOGY, vol. 117, no. 2, August 1999 (1999-08), pages 269-276, XP000989621 ISSN: 0009-9104

D2: VAN DE WAL YVONNE ET AL: "Small intestinal T cells of celiac disease patients recognize a natural pepsin fragment of gliadin." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 95, no. 17, 18 August 1998 (1998-08-18), pages 10050-10054, XP000982626 Aug. 18, 1998 ISSN: 0027-8424

D3: TRONCONE R ET AL: "Cytokines produced by gliadin-specific T cell clones from the coeliac mucosa." GASTROENTEROLOGY, vol. 110, no. 4 SUPPL., April 1996 (1996-04), page A1031 XP000989625 96th Annual Meeting of the American Gastroenterological Association and the Digestive Disease Week;San Francisco, California, USA; May 19-22, 1996 ISSN: 0016-5085

D4: GODKIN A J ET AL: "Identification of a coeliac disease-specific T cell epitope from A-gliadin." GUT, vol. 44, no. SUPPL. 1, April 1999 (1999-04), page A72 XP000989626 British Society of Gastroenterology Annual Meeting;Glasgow, Scotland, UK; March 23-25, 1999 ISSN: 0017-5749

Although no complete examination can be carried out at present (see also point 2 of this invitation), the claims currently on file appear to relate to at least three different inventions:

I) Celiac disease diagnostic methods, agents and kits: independent claims 1, 2, 13, 14, 15, 16, 17 , 21, 22, 25, 26, 27, 28, 38, 40, 41, 42, and the claims dependent thereon;

II) Plant cells, plants and parts of plants that express mutant gliadin proteins, foods

and crops containing such plants: independent claims 31, 35, 46, 47, 48, 49, 51, 52, 53, 54, 55, 57, 58 and the claims dependent thereon;

III) Polynucleotides encoding mutant gliadin, cells transformed with Polynucleotides encoding mutant gliadin, transgenic animals and antibodies against mutant gliadin: independent claims 12, 19, 20, 29, 30, 31, 37 and the claims dependent thereon.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons: The sequence of a natural occurring homologue of gliadin or its analogue (that is the technical feature common to the abovementioned groups of claims) is already known from documents D1 to D4. The requisite unity of invention (Rule 13.1 PCT) therefore no longer exists inasmuch as a technical relationship involving one or more of the same or corresponding special technical features in the sense of Rule 13.2 PCT does not exist between the subject-matter of the abovementioned groups of independent claims.

Thus, this authority finds that the requirement of unity of invention is not met.

2. The attention of the applicant is called to the following:

2.1 The application contains a total of 59 claims, of which 37 are independent claims. In view of the large number and also the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful examination is impossible.

In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a minimum number of independent claims in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).

2.2 The application comprises claims defining the invention in terms of the result to be achieved (example claim 39) which do not comply with the requirements of Article 6 PCT.

2.3 The application comprises claims to methods of diagnostic practised on the human or animal body, as well as claims to methods of treatment practised on the human or

body (example claims 40 and 41). For the assessment of such claims on the question whether they are industrially applicable, no unified criteria exists in the PCT. The patentability can also be dependent upon the formulation of the claims.

3. The applicant is requested to file new claims which take into account the above comments and to make all the necessary amendments in response to this invitation.